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PATENT

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellant : Alan R. Hirsch
Serial No. : 09/211,507
Filing Date : December 14, 1998
For : USE OF ODORANTS TO ALTER BLOOD FLOW TO THE VAGINA
Group Art Unit: 1651
Examiner : C. Tate
Docket No. : INS-31061
Confirmation No.: 9827

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

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Assistant Commissioner for Patents
Washington, D.C. 20231

APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

Sir:

This is an appeal from the final rejection of Claims 1, 2, 4-6, 9-11, 35 and 39-44 of the above-identified application, as set forth in the Office Action mailed June 24, 2002. The Notice of Appeal was timely filed on September 23, 2002.

I. REAL PARTY IN INTEREST

The real party in interest is Alan R. Hirsch.

II. RELATED APPEALS AND INTERFERENCES

Related application Serial No. 09/707,655 is currently under appeal.

III. STATUS OF CLAIMS

Claims 1, 2, 4-6, 9-11, 35 and 39-44 are pending and the subject of this Appeal. The pending claims are provided in the attached Appendix (*Tab A*).

IV. STATUS OF AMENDMENTS

Subsequent to final rejection, a Response after Final Action under 37 C.F.R. § 1.116 was filed on September 6, 2002. Claims 9 and 10 were amended in response to a rejection under 35 U.S.C. § 112(2). In an Advisory Action mailed September 17, 2002, the Examiner withdrew the 35 U.S.C. § 112(2) rejection of Claim 10.

V. SUMMARY OF THE INVENTION

Appellant's invention relates to methods of altering blood flow to the vagina of a female individual through the administration of a mixture of odorants by inhalation.

All of the claims are directed to methods comprising the administration of particular mixtures of odorants: a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, and/or a mixture of baby powder and chocolate odorants.

The methods are described more fully in the detailed description of the invention, and particularly at pages 4-5 and 7. Odorants are described at page 4, lines 9-29, and the Example at page 12, listing commercial sources of the odorants.

Screening of odorants for effectiveness in altering blood flow to the vagina is addressed at pages 7-8, and the Example at pages 8-16. As described in the Example at page 9, a vaginal process graphic recording device, a photophlethysmograph, can be utilized to monitor change in blood flow to the vagina.

The Example at pages 8-16 provides a working example of the application of the odorants recited in the claims to female individuals, and procedures used in assessing the effectiveness of odorants to alter blood flow to the vagina.

VI. ISSUES PRESENTED FOR REVIEW

1. Whether Claims 1, 2, 4-6, 9-11, 35 and 39-44 are unpatentable under 35 U.S.C. § 112, first paragraph, for failing to adequately teach how to make and/or use the invention, i.e., for failing to provide an enabling disclosure.

2. Whether Claims 1, 2, 4-6, 9-11, 35 and 39-44 are unpatentable under 35 U.S.C. § 112, second paragraph, for indefinite claim language.

More specifically, the issue to be decided in this appeal is whether or not Appellant is required to limit the odorants recited in the claims to the specific commercial sources of the odorants disclosed in the Example.

VII. GROUPING OF CLAIMS

For the purposes of this appeal, and in the arguments below, all the claims on appeal are grouped and stand together.

VIII. ARGUMENT

A. Rejection under 35 U.S.C. § 112, first paragraph

In the final Office Action mailed June 24, 2002, and the Advisory Action mailed September 17, 2002, responding to Appellant's Response mailed September 6, 2002, the Examiner rejected Claims 1, 2, 4-6, 9-11, 35 and 39-44 under 35 U.S.C. § 112, first paragraph, stating that Appellant fails to adequately teach the mixtures of odorants claimed, i.e., fails to provide an enabling disclosure. Appellant respectfully requests reversal of this rejection of the claims.

During the prosecution of the present application and its divisional, USSN 09/707,655 (on appeal), the Examiner has maintained this same position concerning the adequacy of the disclosure.

In the second non-final Office Action mailed January 3, 2002, and again in the final Office Action mailed June 24, 2002, the Examiner stated that the claims are enabled only for "the instantly disclosed particular commercial odorants and mixtures thereof" — not for "undefined and/or non-commercial subjective odorants." The Examiner maintained this position

stating that "it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use an odorant having the unusual disclosed/claimed functional effect, other than inhaling one of the particular demonstrated commercial odorants or mixtures thereof..."

1. The Examiner has failed to meet his burden of showing that the claims are not enabled and require undue experimentation.

The Examiner has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling and requires undue experimentation. *In re Angtadt and Griffin*, 190 USPQ 214, 219, 537 F.2d 498, 504 (CCPA 1976).

The Examiner has admitted that the specification is enabling for altering blood flow to the vagina by inhaling "the particular commercial odorants...and/or mixtures thereof instantly demonstrated" disclosed at page 12, lines 1-13.

However, the Examiner requires that the claims be limited to the disclosed commercial odorants based on his contention that the claimed odorants are "undefined" or "subjective" — thus requiring undue experimentation. The Examiner has provided no persuasive reason why the specification does not realistically enable one skilled in the art to practice the invention as broadly as claimed through the use of noncommercial or other commercial sources of the recited odorants. *In re Bowen*, 181 USPQ 48, 51 (CCPA 1974).

First, the claims do not encompass "any undefined odorant and/or non-commercial subjective odorants."

The claims on appeal (*Tab A*) are limited to administering *specified mixtures of odorants*:

- a mixture of a *licorice-based* odorant and *banana nut bread* odorant
- a mixture of a *licorice-based* odorant and *cucumber* odorant
- a mixture of a *lavender* odorant and *pumpkin pie* odorant
- a mixture of a *baby powder* odorant and *chocolate* odorant

The claims are further limited to *odorants that alter blood flow to the vagina*. It is implicit in the claims that the conditions of the method are not met unless the odorant — *licorice, banana nut bread, cucumber, lavender, pumpkin pie, baby powder, chocolate* — achieves the

recited effect. Requiring a recitation in the claims of a specific commercial odorant would be an unnecessary limitation. *In re Dinh-Nguyen and Stenhagen*, 181 USPQ 46, 48 (CCP 1974).

Second, the Examiner's contention that variations in a cucumber odorant according to brand, age/ripeness, a purported and undefined difference in odor between milk chocolate and dark chocolate, etc. is clearly in error and does not provide a basis for requiring the claims be limited to specific commercial embodiments.

The Examiner contends that the recited odorants are highly subjective with respect to the actual odors being encompassed on the basis that:

- a given recipe of pumpkin pie or banana nut bread will vary according to the ingredients,
- baby powder odorants will vary by commercial manufacturer,
- a cucumber odorant will vary according to the brand, species, age/ripeness, and geographic location in which it is grown, etc.,
- a licorice-based odorant such as Good and Plenty™ will have a distinct odor from other licorice based products such as anise, and
- a chocolate odorant such as milk chocolate has a distinct odor from dark chocolate.

Each of the odorants recited in the claims — *licorice, banana nut bread, cucumber, lavender, pumpkin pie, baby powder, chocolate* — will possess a distinct and characteristic aroma or odor that defines the particular odorant.

A cucumber odorant will have a recognizable cucumber odor — regardless of brand, age, etc.

All baby powder odorants will have a similar characteristic odor that is identified and defined as a baby powder odor — regardless of the manufacturer.

A chocolate odorant — regardless of whether it is a milk chocolate or a dark chocolate odorant — will clearly have a chocolate odor.

A licorice-based odorant — exemplified by a Good and Plenty odorant — will not have a distinctive odor from an anise odorant. First of all, anise is a licorice-based odorant — as admitted by the Examiner. Secondly, as evidence by the enclosed copy of a Good and Plenty wrapper (see **Tab B**), a Good and Plenty odorant includes licorice extract and anise flavor as component ingredients.

A pumpkin pie or banana nut bread odorant will each have a characteristic and recognizable pumpkin pie or banana nut bread odor. Variation of "recipe" is necessarily limited to be within the scope of the aroma that is characteristic of the odorant.

Each of the recited odorants — regardless of source — will have a characteristic odor that is within the scope of the aroma that defines the particular odorant as it is understood and employed in the art.

It is well within the ordinary skill in the odorant arts to ascertain non-commercial and other commercial sources of licorice, banana nut bread, cucumber, lavender, pumpkin pie, baby powder, chocolate odorants that fall within the scope of the claims other than the particular demonstrated commercial odorants. Indeed, one of ordinary skill in the odorant arts would be able to readily ascertain whether a substance had a chocolate aroma, a licorice aroma, a banana nut bread aroma, a cucumber aroma, a lavender aroma, or a baby powder aroma — regardless of whether the substance was the commercial source disclosed, or another synthetic or natural source.

Third, the Examiner's repeated referral to Appellant's use of "*an odorant having the unusual disclosed/claimed functional effect*" is no basis for requiring that the claims are limited to specific commercial embodiments of odorants based on undue experimentation.

Appellant submitted a Declaration in response to the Examiner's rejection of lack of utility and non-enablement in which he challenged the believability of Appellant's method and the data provided in Appellant's experimental examples.¹ The results of Appellant's experimental examples, shown in Tables I-V, fully support Appellant's finding that odorants can be administered to a female individual to alter blood flow to the vagina. (Specification at pages 12-15.)

The unusual effect provided by Appellant's method is evidence of the non-obviousness of that method. It does not support a finding of non-enablement of odorants other than the commercial forms disclosed in the specification.

The use of non-commercial and other commercial sources of odorants according to Appellant's method is fully enabled by Appellant's disclosure.

¹ Declaration of Alan R. Hirsch, M.D. submitted July 2, 2001, in response to the Office Action of January, 31, 2001.

Fourth, the varying effects of the odorant mixtures in altering blood flow to the vagina does not provide a basis for requiring the claims be limited to specific commercial embodiments.

The Examiner asserts that the claims should be limited to the commercially identified odorants because the use of other odorants would be highly unpredictable between females. The Examiner bases his reasoning on Appellant's results showing that the same mixture of odorants can cause an increased blood flow to the vagina in some females and a decreased blood flow to the vagina in other females.

First — the Examiner has *not* denied the patentability of the claims based on differing effects. Rather, the Examiner requires that the claims be limited to specific commercial odorants described in Appellant's Example.

Variations in effects are described in the Example at pages 16-17 of the specification.^{2,3}

This variation in effect is the result of characteristics of the female individual — *not* variations in the odorants. As the Example illustrates, it was the variation in a female's response to manual genital stimulation that showed a variation in effect of the licorice-based odorant and cucumber combination.

This does not provide a basis for requiring the claims to be limited to specific commercial embodiments.

² See results at pages 15, lines 1-19:

Women who found manual genital stimulation arousing showed a 12-percent increase in vaginal blood flow in response to pumpkin pie and lavender, and averaged an 18-percent increase with the Good & Plenty® licorice-based odorant and cucumber combination.

No odors induced sexual arousal in the women who were not extremely aroused by manual genital stimulation, whereas many odors inhibited arousal, including male colognes and perfumes, both of which decreased blood flow by 14 percent. The Good & Plenty® licorice-based odorant and cucumber combination decreased blood flow by 13 percent in that group.

³ See discussion at page 16, line 19 to page 17, line 6.

Individual odorants and odorant mixtures that increased vaginal blood flow by about 10-30% ,included ..., a mixture of a licorice-based odorant and banana nut bread odorant, a mixture of a licorice-based odorant and cucumber odorant, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants. These individual odorants and odorant mixtures were particularly effective in increasing vaginal blood flow in those female individuals who are positively sexually aroused with masturbation or by manual manipulation of the genitals:

Odorants can also be administered to decrease vaginal blood flow of a female individual and the level of sexual arousal. The odorants and odorant mixtures that caused a decrease in vaginal blood flow by about 10-20% included ...a mixture of a licorice-based odorant and cucumber odorant, ... These odorants and odorant mixtures were particularly effective in reducing vaginal blood flow in those female individuals who were not sexually aroused with masturbation or by touching or manipulation of the genitals by a partner.

Finally, the disclosure of Doty does not provide a basis for requiring the claims be limited to specific commercial embodiments.

The Examiner cites to Doty (Philadelphia Sensorics, 1983) (*Tab C*) to show that it would be highly unpredictable to use non-commercial or other commercial sources of odorants based on variables such as occupation, general health, psychological state and age of females.

Doty (Philadelphia Sensorics, 1983) describes a test for identifying odorants (the "Smell Identification Test"). According to the test, a male or female subject inhales an odorant and then attempts to identify it. Doty describes (at page 3) conducting five initial experiments to develop the Smell Identification Test™:

Exp. 1: selection of stimuli;

Exp. 2: *examination of influence of variables such as the age, gender, and ethnic background of subjects on the scores of the developed Smell Identification Test™;*

Exp. 3: use of the test to discriminate among person with olfactory disorders;

Exp. 4: determining test-retest reliability; and

Exp. 5: comparison of test scores to results from a traditional detection threshold procedure.

In Experiment 2, male and female subjects were asked to identify (*name*) each of 50 stimulants. A series of multiple regression analyses were performed on the data to determine the influence of age, gender, race and smoking habits on the identification test scores.

At the cited pages 16-18, Doty reported on variations in a person's ability to identify odors based on occupation, general health, and psychological state. Doty also reported that a female's (and male's) ability to smell diminishes with age. (See Tables 1 and 2.)

Appellant's method as claimed is to administering specific odorant mixtures *to alter blood flow to the vagina*.

Doty does not provide any information relating to the physiological effect of odor stimulants. Doty's report of diminished capacity to smell in females with age does not provide any support or indication of a varying physiological effect of odorants between females.

Doty's disclosure does not provide a persuasive reason why the use of non-commercial or other commercial sources of odorants in Appellant's method would be highly unpredictable between females.

The character of the particular odorants recited in the claims is well-delineated, commercial source odorants are identified, and a working example is provided that would enable an art worker to obtain and employ such compounds as broadly as they are claimed, particularly based on the knowledge in the odorant arts. Clearly, one of ordinary skill in the odorant arts would be fully enabled to practice Appellant's invention utilizing both synthetic and natural odorant mixtures from a variety of sources and without undue experimentation.

The Examiner has provided no persuasive reason why the specification does not enable the use of odorants other than the commercial sources exemplified in Appellant's example or would require undue experimentation to use such other sources. Absent such a showing, Appellant's claims should be allowed as sufficiently supported by the specification.

2. Appellant has provided a sufficiently enabling disclosure to meet the requirements of 35 U.S.C. 112, first paragraph.

As stated by the U.S. Court of Customs and Patent Appeals in *In re Borkowski*, 422 F.2d 904, 910, 164 USPQ 642, 646 (CCPA 1970), "there is no magical relation between the number of representative examples and the breadth of the claims; the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode contemplated.'" As further stated by the CCPA, "[t]he sufficiency of the disclosure depends not on the number but rather on the nature of the claimed compounds per se and the nature of the supporting disclosures." *In re Cavallito*, 282 F.2d 363, 367, 127 USPQ 206, 207 (CCPA 1960).

According to Section 112, an Applicant is required to teach how to use an invention, and it is well settled that it is not necessary that the specification disclose every operative example when one skilled in the art is fully apprised by the disclosure of what the invention is and how to use it. A disclosure that contains representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of the claim will possess the described utility is all that is required. The nature of the recited odorants is not ambiguous to one skilled in the odorants arts and would be readily ascertainable.

Appellant has provided a sufficiently enabling disclosure to meet the requirements of 35 U.S.C. § 112(1). Appellant's disclosure provides reasonable assurance to one skilled in the art that odorant mixtures other than the disclosed commercial sources of the odorants will possess the indicated utility and provide the stated effect. That is, Appellant's submit that the specification is sufficiently enabling for one of ordinary skill in the art to make and use the invention disclosed and claimed, and the identification of non-commercial and other commercial sources of the odorants would not require undue experimentation.

The claims are limited to certain mixtures of odorants that alter blood flow to the vagina and thus do not call for just any odorant.

Appellant has described sources of commercial odorants, which are exemplary, that are within the scope of the claims. From the commercially identified odorants and the other information provided by Appellant, one skilled in the odorant arts would readily identify suitable odorants from other sources - both synthetic (e.g., commercial or non-commercial) and natural sources (e.g., essential oils) — that have the odorant characteristic to formulate the recited odorant mixture to achieve the desired effect to alter blood flow to the vagina when inhaled by a female individual.

Known methods in the art can be readily used for identifying and/or preparing odorants within the scope of the claims. For example, it is well known in the art to utilize such methods as gas chromatography-mass spectrometry (GC-MS), among others, to determine the aroma components of an odorant compound. A gas chromatograph distinguishes compounds by comparing to a reference standard.

Appellant in his Response filed on June 3, 2002, submitted publications (Abstracts) that address the identification of aroma components that contribute to various odorants:

Jordan et al., "Aromatic profile of aqueous banana essence and banana fruit by gas chromatography-mass spectrometry (GC-MS) and gas chromatography-olfactometry (GC-O)," *J. Agric. Food Chem.* 49(10):4813-7 (2001) (**Tab D**).

Zhou et al., "Identification and quantification of aroma-active components that contribute to the distinct malty flavor of buckwheat honey," *J. Agric. Food Chem.* 50(7): 2016-21 (2002) (**Tab E**).

Hamilton et al., "Measuring Farmstead Odors," Oklahoma Cooperative Extension Service, OSU Extension Facts F-1740 (06-1999), at (<http://agweb.okstate.edu/pearl/biosystems/general/f1740.htm>) : use of a gas chromatograph with a mass spectrometer detector in odorant analysis (**Tab F**).

Kirk-Othmer Concise Encyclopedia of Chemical Technology, John Wiley & Sons, Inc. (1985) at page 844 : use of instrumental techniques to separate and identify volatile organic substances, for example, capillary gas chromatography columns in tandem with a mass spectrometer, Fourier transform nmr spectroscopy (**Tab G**).

Those of ordinary skill in the art of odor science would readily utilize such known and used instruments as a gas chromatograph with a mass spectrometer detector to identify and/or prepare an odorant as recited in the claims according to an established quality — which in the present application can be ascertained, for example, by utilizing the described commercial source odorants as a comparison. The particular odor ingredients of such odorants mixtures would not vary significantly as the Examiner contends, but would possess a particular "accord" (or "theme") based on particular "notes" according to the particular odorant — as utilized by one of ordinary skill *in the odorant arts*.

The characteristics of the odorants in the mixtures recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorant mixtures from various sources that have the recited odorant character (e.g., mixture of licorice-based and cucumber odorants, etc.) and that would achieve the desired effect of altering blood flow to the vagina when inhaled by a female individual according to Appellant's invention as claimed.

Furthermore, natural sources of the odorants can be utilized in the claimed method. The specification discloses at page 4, lines 16-19, that odorants can be utilized as essential oils— i.e., volatile material isolated from a plant source. Natural sources of odorants are well known in the art and described in various references, for example: *The Merck Index*, 11th Ed., Entry 5261 (lavender) and Entry 4400 (glycyrrhiza), Merck & Co., Inc. (1989); *Remington's Pharmaceutical Sciences*, 18th Ed., Mack Publishing Co., Easton, Pennsylvania (1990) at pages 1294 and 1300; and *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985), pages 810-811. (**Tabs H-J**) Examples of natural sources of the recited odorants include lavender odorant derived from flowers of *Lavandula spica* (*Ilavandula officinalis* or *Lavandula vera*) which contain a volatile oil with the principal constituent *l*-linalyl acetate, and licorice odorant derived from the dried rhizome and roots of *Glycyrrhiza glabra* L., *G. glabra* L. var. *glandulifera*, or other varieties.

Appellant has also described methods that can be used to screen odorants for effectiveness in altering blood flow to the vagina, in the specification at pages 7-8, and in the Example. Screening can be conducted subjectively through interviews with a female subject, or objectively by administering a test to measure initial levels of blood flow to the vagina, re-testing the subject after being given the odorant mixture, and then comparing the results. As described in the Example at page 9, a vaginal process graphic recording device, a photophlethysmograph, can be utilized to monitor change in blood flow to the vagina.

Appellant has fully described an embodiment of his invention and the manner for ascertaining effectiveness. Sources of the recited odorants other than the particular commercial forms disclosed by Appellant could be readily identified and used to practice the claimed invention without undue experimentation. *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied 490 US 1046 (1989).

Satisfaction of the enablement requirement of Section 112 is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." *In re Angstadt and Griffin*, 190 USPQ 214, 219 (CCPA 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Jackson*, 217 USPQ 804 (Bd. App. 1982).

The character of the particular odorants recited in the claims is well-delineated and a working example is provided. It would be a routine matter for one of ordinary skill to obtain and employ other sources of the recited odorants, and readily determine without undue experimentation whether the odorant works or not.

To require Appellant to limit his claims to only those odorants that are expressly exemplified defeats the purpose of the Patent Laws. Such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of experiments. It would also require an inventor to identify every possible commercial and noncommercial source, and synthetic and natural form of the odorants.

Appellant has provided a sufficiently supporting disclosure, both through the working example and descriptive discussion, to teach those of ordinary skill in the art how to make and

use the invention as broadly as it is claimed, and to show that the claimed odorant mixtures are useful in altering blood flow to the vagina of a female individual.

The Examiner has made a determination of non-enablement based on conclusory statements without persuasive reasons or adequate support, and has failed to weigh all of the evidence before him. Appellant has demonstrated that the disclosure as filed would have enabled Appellant's method as claimed for one skilled in the art at the time of filing. The Examiner has failed to consider Appellant's specification including the experimental example providing guidance, and what was well known to one of skill in the art.

Appellant believes that the present disclosure is fully enabling for odorants other than the particular commercial sources described, and requests that the Examiner withdraw the rejection.

B. Rejection under 35 U.S.C. § 112, second paragraph

In the final Office Action mailed June 24, 2002, and the Advisory Action mailed September 17, 2002, responding to Appellant's Response mailed September 6, 2002, the Examiner rejected Claims 1, 2, 4-6, 9-11, 35 and 39-44 under 35 U.S.C. § 112, second paragraph, stating that Appellant fails to adequately define the metes and bounds of the mixtures of odorants claimed, i.e., fails to use definite claim language. Appellant respectfully requests reversal of this rejection of the claims.

The Examiner has maintained this same position concerning indefiniteness in the divisional application, USSN 09/707,655 (on appeal).

In the second (non-final) Office Action mailed January 3, 2002, and repeated in the final Office Action mailed September 17, 2002, the Examiner stated that the odorants are not well understood nor adequately delineated making the claims ambiguous and unclear.

The Examiner merely restated his reasoning under Section 112, paragraph one (enablement), contending that the claimed odorants are highly subjective with respect to the actual odors being encompassed due to variations in recipes of pumpkin pie or banana nut bread, variations in baby powder manufacturers, variations in cucumber brands, species, age/ripeness and geographic locations, a "distinct odor" of Good and Plenty™ from other licorice based products, and a "distinct odor" of milk chocolate compared to dark chocolate.

The Examiner also restated his reasoning that the odorants instantly disclosed and claimed have unusual functional effects, and thus should be limited to the disclosed commercial sources.

1. The Examiner has applied an overbroad interpretation to the language of the claims.

The Examiner has adopted a claim interpretation that ignores the way the terms are used in the art and in the specification.

The standard for interpreting claims during patent prosecution is well-established. Specifically, the standard guiding the USPTO when interpreting claims in an application is:

[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definition or otherwise that may be afforded by the written description contained in the applicant's specification. *In re Morris*, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

Further, a claim that employs well-known language conventionally used in the art to which the invention pertains and which is of the same scope as the description of the invention contained in the disclosure is not objectionable under the second paragraph of 35 USC § 112, since it is neither "too broad" in the sense of embracing a concept not stated in the original disclosure nor is it vague or indefinite. *In re Kamal*, 398 F.2d 867, 870, 158 USPQ 320, 322 (CCPA 1968).

The claims on appeal employ language known and used in the art and which is of the same scope as the described invention. The language of the claims adequately defines the metes and bounds of the claimed invention.

The PTO's interpretation of claim terms should not be so broad that it conflicts with other patents from analogous art. The interpretation that one skilled in the art would give to a disputed term can be demonstrated by the use of the term in other patent references. *In re Cortwright*, 49 USPQ2d 1464 (Fed. Cir. 1999). Indeed, the PTO should not interpret claim terms to have meanings that "conflicts with the meaning given to identical terms in other patents from analogous art." *Id.*

Appellant believes the Examiner's interpretation of the terms "licorice-based odorant," "banana nut bread odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant," ignores the understanding in the art and the meaning given to the terms in other patents, and fails to take into account the description provided in the specification to define those terms.

The specification qualifies the odorants as those that effectively alter blood flow to the vagina. As discussed above, this effect can be readily ascertained by routine screening according to Appellant's provided description and the working example.

The Examiner should reconsider and withdraw his interpretation of the claim language and construe the terms in the claims as those terms are used in the art and understood according to the specification.

2. The art strongly supports Appellant's interpretation of the terms in the claims.

Appellant submits the following documents as evidence of how one skilled in the art uses and understands the terms "licorice-based odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant," and to show the acceptance of these terms in the art, as well as the use and construction applied to these terms by the USPTO. For example, three U.S. patents issued to Appellant Hirsch and U.S. Patent No. 4,463,016 to Burgess use these terms and are in the same U.S. class (424) as the patent application under consideration. Such use demonstrates the acceptance and an understanding of these terms in the art, as well as the construction applied to these terms and understanding of other Examiners in the USPTO.

Importantly, U.S. Patent 5,885,614 (Hirsch) (Use of odorants to treat male impotence...) (**Tab K**) describes a situation similar to the present application where odorants are used and claimed in a *method for increasing penile blood flow in a male individual*. Commercial sources for the odorants are provided in the specification at col. 2, lines 40-43. Several of the presently claimed odorants are recited in the claims, for example, Claims 1 and 2 below (emphasis added):

1. A method of increasing penile blood flow in a male individual, comprising:
 administering to the male by inhalation of an odorant in an amount effective to increase penile blood flow; the odorant selected from the group consisting of orange, a mixture of lavender and pumpkin pie a mixture of doughnut and black licorice, a mixture of pumpkin pie and doughnut lily of the valley, black licorice, a mixture of doughnut and cola, a mixture of

black licorice and cola, a mixture of lavender and doughnut, chocolate, strawberry, rose, green, apple, parsley, peppermint, musk, lavender, vanilla, cranberry, pink grapefruit, floral, baby powder, oriental spice, cinnamon buns, roasting meat, cheese pizza, doughnut, cola, pumpkin pie, and buttered popcorn.

2. A method of increasing penile blood flow in a male individual, comprising:
 administering to the male by inhalation of an odorant in an amount effective to increase penile blood flow; the odorant selected from the group consisting of a mixture of lavender and pumpkin pie, a mixture of doughnut and black licorice, and a mixture of pumpkin pie and doughnut.

U.S. Patent 5,759,521 (Hirsch) (Method of altering perception of relative space of an area) (**Tab L**) identifies a cucumber odorant as useful (col. 1, line 66 to col. 2, lines 3 and lines 31-34:

"...a substance having the characteristics of a green apple odorant, cucumber odorant, or seashore odorant is administered to a patient to cause the patient's perception of a confined area to become altered and expanded..."

and commercial sources of the odorants (at col. 2, lines 45-47).

U.S. Patent 6,106,837 (Hirsch) (Method of treating headaches...) (**Tab M**) identifies lavender odorant as useful and provides several commercial sources of the odorants (at col. 3, lines 31-37):

An example of such an odorant is a substance having the characteristic of a green apple odor such as isoamyl isovalerate. Other useful odorants include, for example, banana, peppermint, and lavender. Such odorants are available commercially, for example, from International Flavors and Fragrances, Inc. (IFF, New York, N.Y.), Energy Essentials, Aroma Tech, and as essential oils.

U.S. Patent 4,463,016 (Burgess) (Method for the treatment of razor bumps) (**Tab N**) describes a topical composition that can include a "fragrance such as cucumber fragrance No. 24." See col. 2, line 59. The odorant is also recited in Claim 6 below (emphasis added):

1. A method for the treatment of razor bumps which comprises topically administering to an individual suffering from razor bumps an effective amount of a compound of the Formula: [formula] wherein R₁ and R₂ are C₁–C₇ alkyl in combination with a vehicle which facilitates topical application of the compound of Formula I.

6. The method according to claim 5 wherein said vehicle is composed of ingredients selected from the group consisting of propylene glycol, purified water, lanolin, sodium stearate, polyethylene glycol monostearate, sesame oil, cetyl alcohol, methyl paraben, propyl paraben, camphor and cucumber fragrance.

Also importantly, the Doty publication (Philadelphia Sensorics, 1983) — cited by the Examiner — lists *licorice*, *chocolate*, and *pumpkin pie odorants*, among others (Doty at page 7) (*Tab C*).

Such use clearly shows that one skilled in the art uses and understands the terms "licorice-based odorant," "banana nut bread odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant." Equally important, the above patents, particularly USP 5,885,614 issued by the USPTO with claims to a method to increase penile blood flow, (*Tab K*) demonstrate that the presently used odorant terms are accepted and well understood in the art and by the USPTO.

The terms licorice, cucumber, lavender, pumpkin pie, baby powder, and chocolate odorants have been utilized in various contexts including Applicant's own issued patents as well as other issued patents and publications — *including the cited Doty publication (Tab C* — see at page 7 listing licorice, chocolate, pumpkin pie odorants), for example.

As such, the Examiner's interpretation of the claims is overbroad in view of how the term is used and understood by one skilled in the art and conflicts with the meaning give to identical terms in other patents from analogous art.

3. The Examiner has failed to take into account the written description and the limitations in the claims when interpreting the meaning of the terms of the claims.

The specification clearly states that the odorants and odorant mixtures are capable of altering blood flow to the vagina when inhaled by a female individual, and this feature is recited in the claims.

The nature of the recited odorants is well understood in the odorant arts, and one skilled in the odorant arts would readily identify suitable odorants from various sources – both synthetic and natural – that have the recited odorant character and would achieve the desired effect. As recited in the claims, suitable odorant mixtures are those having the recited characteristic of a mixture of: a) a licorice-based odorant and banana nut bread odorant, b) a licorice-based odorant and a cucumber odorant, c) a lavender odorant and a pumpkin pie odorant, and d) a baby powder odorant and a chocolate odorant, which are capable of altering blood flow to the vagina when inhaled by a female individual.

The above arguments demonstrate that the inventor clearly uses the terms "licorice-based odorant," "banana nut bread odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant" as such terms are commonly used in the art. The Examiner improperly interprets the claim limitations as being overbroad.

One skilled in the odorant arts reading the claims would understand the metes and bounds of those terms in the claims when read in light of the specification, which sets forth examples for such odorants, and in view of the knowledge in the art, as evidenced by Applicant's issued patents and Doty's publication, among others. It is respectfully submitted that the nature and identity of the recited odorants is not ambiguous to one skilled in the odorants arts.

Based on Appellant's disclosure and the understanding in the art, the Examiner's finding that the claims are indefinite is in error. One of ordinary skill in the art would readily identify and use both synthetic and natural sources of the recited odorants other than the commercial sources of odorants disclosed in the specification according to the claimed method.

As such, Appellant believes that the claims are clear in their meaning and that the language of the claims is definite and correct, and requests that the Examiner withdraw the rejection.

IX. REQUEST

For the reasons stated in the above argument, Appellant believes that the claims on appeal comply with 35 U.S.C. § 112, and requests that the final rejection of the claims on appeal be reversed.

Respectfully submitted,



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APPENDIX

- A) Claims on Appeal.
- B) Copy of Good and Plenty® wrapper.
- C) Doty (Philadelphia Sensorics, 1983).
- D) Jordan et al., "Aromatic profile of aqueous banana essence and banana fruit by gas chromatography-mass spectrometry (GC-MS) and gas chromatography-olfactometry (GC-O)," *J. Agric. Food Chem.* 49(10):4813-7 (2001)
- E) Zhou et al., "Identification and quantification of aroma-active components that contribute to the distinct malty flavor of buckwheat honey," *J. Agric. Food Chem.* 50(7): 2016-21 (2002).
- F) Hamilton et al., "Measuring Farmstead Odors," Oklahoma Cooperative Extension Service, OSU Extension Facts F-1740 (06-1999), at (<http://agweb.okstate.edu/pearl/biosystems/general/f1740.htm>) : use of a gas chromatograph with a mass spectrometer detector in odorant analysis.
- G) *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985) at page 844 : use of instrumental techniques to separate and identify volatile organic substances, for example, capillary gas chromatography columns in tandem with a mass spectrometer, Fourier transform nmr spectroscopy.
- H) *The Merck Index*, 11th Ed., Entry 5261 (lavender) and Entry 4400 (glycyrrhiza), Merck & Co., Inc. (1989).
- I) *Remington's Pharmaceutical Sciences*, 18th Ed., Mack Publishing Co., Easton, Pennsylvania (1990) at pages 1294 and 1300.
- J) *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc. (1985), pages 810-811.
- K) U.S. Patent 5,885,614 (Hirsch) (Use of odorants to treat male impotence...).
- L) U.S. Patent 5,759,521 (Hirsch) (Method of altering perception of relative space of an area).
- M) U.S. Patent 6,106,837 (Hirsch) (Method of treating headaches...).
- N) U.S. Patent 4,463,016 (Burgess) (Method for the treatment of razor bumps).